



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement:

Gene Therapy and Cell-Based Therapy for Cardiac Arrhythmias

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to Pace Biologics, LLC, a company having a place of business in ElkrIDGE, Maryland, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/180,491, filed May 22, 2009 (HHS Ref. No. E-134-2009/0-US-01), PCT Patent Application No. PCT/US2010/035823, filed May 21, 2010 (HHS Ref. No. E-134-2009/0-PCT-02), and U.S. Patent Application No. 13/322,066, filed November 22, 2011 (HHS Ref. No. E-134-2009/0-US-03), all entitled “Engineered Biological Pacemakers.” The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Evaluation Option

License Agreement may be worldwide, and the field of use may be limited to “Gene therapy and cell-based therapy for cardiac arrhythmias in humans.”

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, Pace Biologics will have the exclusive right to execute a Start-Up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application(s), inquiries, comments and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4426; Facsimile: (301) 402-0220; E-mail: tarak@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This invention consists of biological pacemakers engineered to treat arrhythmia by generating a normal heart rhythm. These pacemakers include viral vectors suitable for gene therapy that incorporate Ca^{2+} -activated adenylyl cyclase, as well as cardiac cells or cardiac-like cells derived from embryonic stem cells or mesenchymal stem cells, which are suitable for cell-based therapy.

In contrast to implantable artificial pacemakers, these biological pacemakers are not externally powered, are not subject to interference from other devices, and have a lower risk of infection. They would be particularly appropriate for patients who are not candidates for artificial pacemakers, such as children or those who have had an implantable pacemaker removed due to complications or other problems.

The prospective Start-Up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective Start-Up Exclusive Evaluation Option License Agreement and a subsequent Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice that establishes, that the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent

permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C.
552.

May 2, 2013
Date

Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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